ATTACHMENT B

REMARKS

By this amendment, Applicants have canceled Claim 22 in order to overcome the claim objection. For reasons as set forth below, the invention as presently claimed in not disclosed or remotely suggested in the prior art, and the present application is now allowable for at least the following reasons.

In the Official Action, the Examiner objected to Claim 22 as duplicative, and this claim is now canceled without prejudice in that the subject matter of this claim is found in Claim 1.

In the Official Action, the Examiner rejected Claims 1-14, 18 and 22-26 under 35 U.S.C. § 112, on the basis that the invention "was not described in the specification in such a way as to reasonably convey to one skilled in the relevant are that the inventor(s), at the time the application was filed, had possession of the claimed invention." This rejection is respectfully traversed.

The requirement under 35 U.S.C. § 112 is that every patent must contain a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention. Where the invention involves a biological material, it is only when the invention cannot "sufficiently describe how to make and use the invention in a reproducible manner" is a biological deposit required. Applicants submit that the invention as presently claimed, isolated antibodies which can bind to the Map10 protein, is clearly described in the application sufficient so that one skilled in the art would instantly be aware of the invention and would know how to obtain it in a reproducible manner. Indeed, the Map10 protein is clearly disclosed in

the application, and it would be routine using the teachings of the invention to generate and to identify antibodies in accordance with the invention. Further, the Examiner concedes at Page 9 of the Official Action that "it is well known in the art that the Western immunoblot is a method that identifies antibodies against proteins of a particular molecular weight. . ."[1]

The case law is in accordance. This specific issue arose in Evans Medical Ltd. v. American Cyanamid Co., 52 USPQ2d 1455 (Fed. Cir. 1999), and the Federal Circuit noted in that case that "during prosecution of the '080 patent the examiner explicitly stated that as making an antibody against the 69kD antigen was within ordinary skill, no deposit was required." 52 USPQ2d at 1460. Similarly, with regard to the present invention, it is clear that one skilled in the art will recognize that the claimed antibodies to Map10 are sufficiently described, and would have no trouble generating and identifying such antibodies in accordance with the invention. As a result, a deposit in this case is not needed, and the claims in their present form are proper under 35 U.S.C. § 112.

In the Official Action, the Examiner rejected Claims 10, 12 and 24 under 35 U.S.C. § 112, on the basis that the claims "contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant are that the inventor(s), at the time the application was filed, had possession of the claimed invention." In particular, the Examiner objected to the use of the term "or degenerates thereof" with regard to nucleic acid sequences and stated that

[1] The protein disclosed in the cited Hook et al. patent is <u>not</u> the Map10 protein of the present invention and thus that references does not disclose or suggest the present claims for reasons discussed further below.

other than the specific nucleic acid sequences "the skilled artisan cannot envision the detailed structure of the degenerates thereof ". This rejection is respectfully traversed.

With regard to the "skilled artisan" not "envisioning" the structure of nucleic acid degenerates as called for by the claim, such a statement is ludicrous in light of the fact that the "Genetic Code" which allows one to determine the different nucleic acid sequences coding for the same amino acid (see Appendix A) has been well known for several decades. Accordingly, once a protein sequence (i.e., amino acid sequence) is known, the skilled artisan instantly knows that there are a fixed number of nucleic acid codons which code for particular amino acids, and that there are thus a fixed number of nucleic acid sequences, considered "degenerates" of each other, which will all code for the same protein/amino acid sequence. The skilled artisan would thus have no problem whatsoever in recognizing the specific structures of the nucleic acid sequences of the invention which code for the protein sequences of the invention. With this in mind, it is noted that a myriad of other cases involving nucleic acid sequences coding for proteins have also been issued with claims including a reference to nucleic acid sequences and their degenerates. See U.S. Pat. Nos. 5,916,572; 6,008,341; 6,521,413; and 6,177,084, copies of claims provided as Appendix B. Indeed, the specific case cited by the examiner, Board of Regents v. Eli Lilly, 43 U.S.P.Q.2d 1398-1412, is totally inapposite since the claims in that case were not to a specific sequence.

Accordingly, this rejection has been respectfully traversed and should be withdrawn.

In the Official Action, the Examiner rejected Claim 2 on the grounds that the specification was enabling only for the monoclonal antibody H07 to prevent or treat

infection in *S. aureus.* The Examiner pointed out that while antibody H07 showed excellent results in treating infections, H01 did not appear to have such efficacy. This rejection is respectfully traversed. In the first place, the Examiner concedes that Applicants' results show that the antibodies of the present invention can be used in treating or preventing infection of *S. aureus.* Moreover, the Examples also show efficacy of other antibodies, including H04 and H10 which provided "significant protection" against infection. Accordingly, the invention is clearly enabled for one of ordinary skill in the art to use the antibodies in methods of treatment or prevention. In addition, the tests as shown, e.g., in Example 2, are routine, and thus one skilled in the art will be able to test the efficacy of particular antibodies of the invention using routine means to screen for other antibodies in addition to H04, H07 and H10 to be used in treatment. Even where necessary, such routine steps to determine the efficacy of a particular strain still means that the invention is satisfactory under 35 U.S.C. § 112 pursuant to In re Wands.

Accordingly, this rejection has been respectfully traversed and should be withdrawn.

Finally, in the Official Action, the Examiner rejected Claims 1-4 under 35 U.S.C. §102(b) as being anticipated by Hook et al. U.S. Pat. No. 5,648,240. The basis of this rejection is the Examiner's assertion that "The gene and protein of the instant application designated as Map10, is the same gene and protein of US Patent 5,648,240. See the instant specification at page 5." This rejection is respectfully traversed.

In short, the Examiner's assertion that the Map10 protein disclosed and claimed in the application is disclosed in the Hook patent is simply wrong. To the contrary, neither Map10 nor any antibodies thereto has been disclosed in any prior art reference, much less the Hook et al. US patent 5,648,240 which does not disclose the Map10 protein nor raise any antibodies to it. The Hook et al. US patent 5.648,240 merely relates to the cloning and sequencing of the whole "MAP" protein and not to the specific Map10 protein, and moreover, this patent does not provide any disclosure or suggestion by which one skilled in the art would use to obtain the very specific Map10 protein binding subdomain of the present invention.

Even further, Examples 6 and 9 of Hook et al. US patent 5,648,240, which were cited by the Examiner as allegedly showing the claimed Map10 antibody, in fact merely relate to a purified peptide from the broad spectrum adhesin which is not Map10 (Example 6), and to the MHC-II analog protein which is the entire MAP protein (Example 9) and which once again does not disclose or suggest the present claims which refer to the specific Map10 protein. Thus, the Map10 protein and its antibodies have simply not been disclosed or suggested in the cited reference.

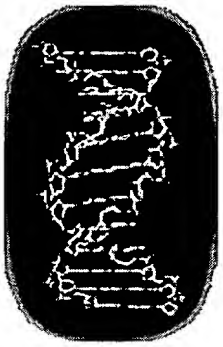
Accordingly, in light of the fact that Hook neither discloses nor remotely suggests the specific Map10 protein bound by the antibodies of the present invention, and this reference clearly cannot anticipate or make obvious the present invention, and the Examiner's rejection on the basis of this reference is respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

END REMARKS

APPENDIX A

The Genetic Code



First Position	Second Position of Codon: T	Second Position of Codon: C	Second Position of Codon: A	Second Position of Codon: G	Third Position
T	TTT Phe [F]	TCT Ser [S]	TAT Tyr [Y]	TGT Cys [C]	T
	TTC Phe [F]	TCC Ser [S]	TAC Tyr [Y]	TGC Cys [C]	C
	TTA Leu [L]	TCA Ser [S]	TAA *Ter* [end]	TGA *Ter* [end]	A
	TTG Leu [L]	TCG Ser [S]	TAG *Ter* [end]	TGG Trp [W]	G
C	CTT Leu [L]	CCT Pro [P]	CAT His [H]	CGT Arg [R]	T
	CTC Leu [L]	CCC Pro [P]	CAC His [H]	CGC Arg [R]	C
	CTA Leu [L]	CCA Pro [P]	CAA Gln [Q]	CGA Arg [R]	A
	CTG Leu [L]	CCG Pro [P]	CAG Gln [Q]	CGG Arg [R]	G
A	ATT Ile [I]	ACT Thr [T]	AAT Asn [N]	AGT Ser [S]	T
	ATC Ile [I]	ACC Thr [T]	AAC Asn [N]	AGC Ser [S]	C
	ATA Ile [I]	ACA Thr [T]	AAA Lys [K]	AGA Arg [R]	A
	ATG Met [M]	ACG Thr [T]	AAG Lys [K]	AGG Arg [R]	G
G	GTT Val [V]	GCT Ala [A]	GAT Asp [D]	GGT Gly [G]	T
	GTC Val [V]	GCC Ala [A]	GAC Asp [D]	GGC Gly [G]	C
	GTA Val [V]	GCA Ala [A]	GAA Glu [E]	GGA Gly [G]	A
	GTG Val [V]	GCG Ala [A]	GAG Glu [E]	GGG Gly [G]	G

An explanation of the Genetic Code: DNA is a two-stranded molecule. Each strand is a polynucleotide composed of **A** (adenosine), **T** (thymidine), **C** (cytidine), and **G** (guanosine) residues polymerized by "dehydration" synthesis in linear chains with specific sequences. Each strand has polarity, such that the 5'-hydroxyl (or 5'-phospho) group of the first nucleotide begins the strand and the 3'-hydroxyl group of the final

nucleotide ends the strand; accordingly, we say that this strand runs 5' to 3' ("*Five prime to three prime*") . It is also essential to know that the two strands of DNA run *antiparallel* such that one strand runs 5' -> 3' while the other one runs 3' -> 5'. At each nucleotide residue along the double-stranded DNA molecule, the nucleotides are complementary. That is, **A** forms two hydrogen-bonds with **T**; **C** forms three hydrogen bonds with **G**. In most cases the two-stranded, antiparallel, complementary DNA molecule folds to form a helical structure which resembles a spiral staircase. This is the reason why DNA has been referred to as the "Double Helix".

One strand of DNA holds the information that codes for various genes; this strand is often called the template strand or antisense strand (containing anticodons). The other, and complementary, strand is called the coding strand or sense strand (containing codons). Since mRNA is made from the template strand, it has the same information as the coding strand. The table above refers to triplet nucleotide codons along the sequence of the coding or sense strand of DNA as it runs 5' -> 3'; the code for the mRNA would be identical but for the fact that RNA contains **U** (uridine) rather than **T**.

An example of two complementary strands of DNA would be:

(5' -> 3') **ATGGAATTCTCGCTC** (Coding, sense strand)
(3' <- 5') **TACCTTAAGAGCGAG** (Template, antisense strand)

(5' -> 3') **AUGGAAUUCUCGCUC** (mRNA made from Template strand)

Since amino acid residues of proteins are specified as triplet codons, the protein sequence made from the above example would be Met-Glu-Phe-Ser-Leu... (MEFSL...).

Practically, codons are "decoded" by transfer RNAs (tRNA) which interact with a ribosome-bound messenger RNA (mRNA) containing the coding sequence. There are 64 different tRNAs, each of which has an anticodon loop (used to recognize codons in the mRNA). 61 of these have a bound amino acyl residue; the appropriate "charged" tRNA binds to the respective next codon in the mRNA and the ribosome catalyzes the transfer of the amino acid from the tRNA to the growing (nascent) protein/polypeptide chain. The remaining 3 codons are used for "punctuation"; that is, they signal the termination (the end) of the growing polypeptide chain.

Lastly, the Genetic Code in the table above has also been called "The Universal Genetic Code". It is known as "universal", because it is used by all known organisms as a code for DNA, mRNA, and tRNA. The universality of the genetic code encompasses animals (including humans), plants, fungi, archaea, bacteria, and viruses. However, all rules have their exceptions, and such is the case with the Genetic Code; small variations in the code exist in mitochondria and certain microbes. Nonetheless, it should be emphasized that these variances represent only a small fraction of known cases, and that the Genetic Code applies quite broadly, certainly to all known nuclear genes.